COMPARISON OF PRE AND POST OPERATIVE NASAL ANTHROPOMETRIC MEASUREMENTS AND SUBJECTIVE ASSESSMENTS IN ADULT PATIENTS UNDERGOING PRIMARY RHINOPLASTY



THESIS

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DECLARATION

I, hereby declare that the work reported in the thesis titled – "COMPARISON OF PRE AND POST OPERATIVE NASAL ANTHROPOMETRIC MEASUREMENTS AND SUBJECTIVE ASSESSMENTS IN ADULT PATIENTS UNDERGOING PRIMARY RHINOPLASTY" embodies the result of an original research work done by me in the Department of Otorhinolaryngology, All India Institute of Medical Sciences, Jodhpur.

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CERTIFICATE

This is to certify that the thesis titled "COMPARISON OF PRE AND POST **OPERATIVE** NASAL **ANTHROPOMETRIC MEASUREMENTS** AND SUBJECTIVE ASSESSMENTS IN ADULT PATIENTS UNDERGOING PRIMARY RHINOPLASTY" is the bona fide work of Dr. Abir Chowdhury carried out under guidance our and supervision, in the Department of Otorhinolaryngology, All India Institute of Medical Sciences, Jodhpur.

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DEDICATED TO MY FAMILY, MY TEACHERS

AND

MY FELLOW COLLEAGUE

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INTRODUCTION

All humans have a craving for beauty since the beginning of time. It contributes to a person's well-being and is necessary for gaining strength, courage, and confidence. The word aesthetic is derived from the Greek word aesthesis, which implies a great sense of or commitment to beauty. Greek philosophers believed that beauty was an important component of the ideal cosmos, and they attempted to define it using the same mathematical methods and geometric relationships that were used to create the natural law (1).

Anthropometry has evolved as a result of a growing interest in determining human anatomy variances (2). Anthropometry is a set of systematic measurement techniques for quantifying the human body and skeleton measures. Face anthropometry has become an important tool in genetic counseling, reconstructive surgery, and forensic investigation (3-5). The nose is the most prominent feature of the face, and it plays an important part in establishing a beautiful appearance. Anthropometry of facial symmetry and proportions is regarded as a factor of beauty in a particular population (6). The nose is the most identifying feature of an individual as it's located in the center of the face (7). Races, tribes, and geographical places have different nose shapes on the basis of the nasal slope, bridge, tip broadness, nares, and septum. As a result, the nose is a signature that identifies an individual's ethnicity, race, age, and gender (8-11). Previous anthropometric studies reveal that there are many differences between the ethnic and racial groups, and they have compared the individual variations in both sexes (12). Different nose traits are partly the result of evolutionary adaption to the climate in different parts of the world (13).

Other factors that influence nasal features include genetics, race, and so on. The measuring of several nasal characteristics is known as nose anthropometry. Nasal size has been linked to oxygen consumption (14) and the nasal index has been linked to average temperature and humidity (15, 16). Nasal index approximately represents the ratio of the breadth of the nasal aperture to its height. Cold and dry climates were linked to a low nose index, while hot and humid climates were linked to a high nasal index. It is unknown whether differences in nose size and shape between ethnic groups affect nasal physiology or predisposition to sino-nasal pathology (17).

Direct anthropometry procedures are time-consuming, with issues such as patient adaption, measurement repeatability, and data preservation. Indirect measurement technologies such as photography, cephalography, stereo photography, laser scanning, and computerized tomography have gained in popularity as a result. Photography is one of the most commonly utilized clinical tools. It's a simple, low-cost strategy that improves patient compliance (12). We used the photographic method of anthropometric evaluation in our research as well.

It is critical to examine the type of nose that is distinctive of a certain race or ethnic group when planning rhinoplasty in order to match the final result with the proportions of the face. Rhinoplasty surgeons need accessibility to facial data based on exact anthropometric measurements in the ability to accomplish effective correction in both sexes (12). There are numerous differences in the shapes and nasal anatomy between males and females. Hence, feminization of a male nose is not a desirable result. Accurate preoperative planning and awareness of these morphological differences are essential for a successful rhinoplasty. Anthropometric analysis of the nose shows us the way to provide satisfactory results of the cosmetic nasal surgery (12).

A surgically repaired nose should blend in with the individual's ethnic facial features (18). India is a country with a wide range of cultures and ethnic groups. There hasn't been a single focused study that specifies the aesthetic anthropometric measurements in order to give standards for Indian rhinoplasty till now. Because it is in the center of the face, the nose is the most distinguishing characteristic of a person. The nose's form is a hallmark that reveals ethnicity, race, age, and gender.

This topic could not be answered solely in terms of a largely cosmetic or functional operation when the statistical analysis was done based on patient motivations for surgery and their satisfaction or discontent with the outcome. As a result, Haas coined the phrase "corrective rhinoplasty."(19). Facial plastic surgeons measure success of the surgical technique based on qualitative evaluations. However, there is a lack of a standardized qualitative assessment making it extremely difficult to compare objectively the success of different techniques and individual surgeons. (20)

Due to improved self-consciousness, media awareness, and advancements in surgical maneuvers, the demand for aesthetic rhinoplasty has risen dramatically throughout Asia during the last two decades. The tendency has had the greatest impact on men and women in their twenties and thirties (21). This is one of the most technically

difficult procedures in the field of plastic surgery. The surgeon must have a thorough understanding of the underlying anatomy, be able to undertake a naso-facial examination to decide the best course of action and be able to handle bone, cartilage, and soft tissue. These methods are used with an aesthetic eye to produce a result that suits the rest of the face (22).

Patient happiness is influenced by gender, age, education level, culture, ethnicity, and, most importantly, the patient's level of expectation (23). In preoperative evaluation, the main focus is on assessing elements that contribute to the patient's pleasure. The post-rhinoplasty satisfaction percentage is poor due to the variety of the treatment and the difficulties in assessing patient expectations. A recent found that males were more ambiguous when expressing reasons for their dissatisfaction, than females. The males were found to have a lower satisfaction with the surgery. Females were significantly more likely to precisely vocalize their morphologic or functional reason for dissatisfaction. (24). In rhinoplasty, patient selection is critical since, despite an excellent surgical result, a large percentage of patients may not be pleased (25).

This study aims at the comparison of pre and post-operative nasal anthropometric measurements and subjective assessment in patients undergoing primary rhinoplasty.

"The qualities of measure and proportion invariably constitute beauty and excellence"- Plato (527-347 BC)

REVIEW OF LITERATURE

History of Rhinoplasty:

Sushruta is known for inventing rhinoplasty. He's also renowned as the "Father of Indian Surgery" and the "Father of Indian Plastic Surgery," among other titles. The process of rhinoplasty is properly explained by Sushruta in the classic ancient encyclopedic treatise "SushruthSamhita". In Indian tradition, the amputation of the nose was a common punishment for criminals, war prisoners, and anyone who had committed adultery. So, from that moment forward, rhinoplasty surgery was gradually implemented to reconstruct the exterior nose. Rhinoplasty became well-known from India to Arabia, Persia, and, lastly, Egypt. Rhinoplasty concepts and methods spread centuries ago throughout Europe and the rest of the world (26)

It took centuries for rhinoplasty concepts and procedures to spread throughout Europe and the rest of the world. The modification of Sushruta's cheek flap to a rotating forehead flap was a traditional Indian form of rhinoplasty that has been practiced for generations in India by the Kanghairas of Kangra (Himachal Pradesh), the Marathas of Kumar near Poona, and certain Nepali families (27)

Following this, a stagnant period of nearly 200 years ended with the revival of the art of rhinoplasty, as a result of a letter published in the Gentleman's Magazine of London in 1794 (28).

Killian and Freer initiated the submucous resection septoplasty procedure to correct a deviated septum, elevating mucoperichondrial flaps and surgically removing the cartilaginous and bony septum (including the ethmoid bone's perpendicular plate and vomer), sustaining septal support with a 1.0-cm margin. The open rhinoplasty procedure, which includes making a nasal septum incision to modify the tip of the nose, was invented by A. Rethi in 1921 (29).

When Padovan demonstrated his technological breakthroughs, backing the open rhinoplasty approach, which was backed by Wilfred S. Goodman in the 1970s and Jack P. Gunter in the 1990s, endonasal rhinoplasty fell out of favor (30).

Goodman paved the way for technological and procedural advancements, as well as popularising the open rhinoplasty method (31).

For the treatment of complex nasal abnormalities, external rhinoplasty is a physiologically sound procedure that has various advantages over endonasal access (32).

When evaluating a patient for rhinoplasty, it's important to look at the whole picture rather than just the nose. The examination begins as soon as the patient enters the consultation room and is formalized before a thorough examination of the nose. Attractive faces are thought to have optimal measurements and angles, which are said to be based on Leonardo da Vinci's dimensions (33, 34). Albrecht Duerer (35), Powell, and Humphrey (36) have since expanded on this concept.

Although modest asymmetry may be related to the perception of beauty, facial symmetry is said to provide the foundation for a beautiful face (37). Many patients are unaware of small facial asymmetries, which can lead to unhappiness and misunderstanding if they are discovered during the post-operative period. As a result, it's critical to discuss these concerns with the patient and document them prior to surgery.

While a rhinoplasty on an asymmetrical face can result in post-surgery unhappiness, fixing an asymmetrical nose that gives the illusion of facial asymmetry can enhance facial symmetry without the need for any other surgical procedures (38, 39).

The optimal angles of the facial aesthetic triangle were described by Powell and Humphrey (36). The following are the recognized dimensions of each of the facial angles:

- Naso-frontal angle 115–135 °
- Naso-facial angle 30–40 $^\circ$
- Naso-mental angle 120–132 °
- Mento-cervical angle 80–95 °C

Facial proportions serve as a reference and aid in operation planning, but they should not be treated as absolutes. Each rhinoplasty should take into account the patient's wishes, gender, and personality. It's also crucial to note that these ideal measurements differ by ethnicity (40).

Naso-facial angle:

A questionnaire was used in one study, as well as a method for determining ideal and normative values. A naso-facial angle of around 30 was found to be best, with a range of 27-36 being considered acceptable. Angles that were above or below this range were deemed unappealing. Angles beyond the 21–42 range were regarded as unattractive. The most unattractive feature was excessive nasal prominence (a nasal angle of 48 degree. A minimum value within the range of 24 to 39 degree indicated a preference for surgery in all groups, despite clinicians being the least likely to advice for surgery (41).

The naso-facial angle was 32.3 in Korean (42) females, 35.5+/-0.38 in the Nigerian Yoruba ethnic group, and 36.3 +/-0.37 in the Ibo ethnic group (43).

Naso-frontal angle:

Nasion: It's crucial to figure out where the nasion should be in its best location. The term "nasion" refers to a specific spot in the naso-frontal groove that is around 4–6 mm deep in reference to the glabella (44).

With the eyes in forwarding gaze, the deepest region of the naso-frontal angle should be between the top eyelash line and the supratarsal fold. Because there are no established standards for evaluating the proper angle depth, the surgeon must rely on his or her aesthetic judgment to determine if the angle is too shallow or too deep (45).

The size and shape of the naso-frontal angle are determined by a variety of factors (46). Among the factors are:

- The glabellar area's shape and size.
- The position of the eyebrows
- The width, depth, slope lengths, and surface contour of the nasal root, as well as the relationship of its bottom point to the intercanthal line level, are all contoured by the distance between the glabella level and the deepest point of the root.
- The nasal bridge's length and inclination.

The naso-frontal angle may play a role in the sense of beauty in facial profiles. Drawing a line from the nasion tangent to the glabella and another line tangent to the nasal dorsum, intersecting at the nasion, yields the naso-frontal angle. In profile view, the angle can be utilized to examine the relationship between the glabellar region and the nasal dorsum. The anatomy of the nasal bridge and glabellar region will determine the size of this angle. An idealized male Caucasian naso-frontal angle is 106 to 148.

A naso-frontal angle of roughly 130 degrees is desirable, with a range of 127 to 142 degrees being considered acceptable, according to one study. Angles outside of this range are considered unsightly, and anything outside of 118 to 145 degrees is considered extremely unpleasant. Reduced naso-frontal angles of fewer than 115 degrees, which simulate a nasal hump deformity, were deemed the least appealing. In terms of desire for surgery threshold values, a value above 148 degrees indicated a preference for surgery in all categories. (47).

Similarly, in the Turkish study (48), the naso-frontal angle in males was 123.85 ± 13.23 and in females, it was 133.16 ± 8.88 .

Naso-labial angle:

Naso-labial angle (NLA), as described by Guyuron, is measured by dropping a perpendicular line from the Frankfurt Horizontal line through the sub-nasale (49). The angle is formed by intersecting another line through the most anterior and posterior portions of the nostril.

Tip rotation plays a critical role in the overall aesthetic appearance of the nose as well. The rotation of the tip is determined by the naso-labial angle. This is determined by drawing a horizontal line through the most anterior and posterior points of the nostrils. The angle that exists between this line and the line perpendicular to the natural horizontal facial plane is considered the naso-labial angle. They prefer a naso-labial angle of 95 to 110 degrees in women and 90 to 95 degrees in men (50).

One study was performed where wide skeletonization was performed in all 50 patients as the preferred method. It caused an increase in the naso-labial angle angle. The effect of skeletonization on nasal tip projection was not considerable. Two to four millimeters of the lower lateral cartilage were conservatively resected in all cases as cephalic resection. It caused a decrease of 1.9 degrees of naso-labial angle and 0.53 mm of nasal tip projection.1. An 18-to 22-mm strut was formed from septal cartilage and placed in all patients as a columellar strut. On average, naso-labial angle increased by 4 degrees, and nasal tip projection by 0.31 mm. Tip-spanning sutures were performed in 18 patients. It resulted in a 0.84-mm increase in nasal tip projection and it did not affect the naso-labial angle (51).

Columellar strut graft: Historically, it was thought that columellar strut graft would increase tip projection, but one retrospective study was performed regarding columellar strut graft and it was noticed that tip projection decreased in 65 percent, increased in 27 percent, and was unchanged in 8 percent of subjects. The naso-labial angle was increased by 46 percent, decreased by 34 percent, and unchanged in 20 percent (52). So it has been concluded that the use of the columellar strut cartilage graft does not necessarily imply an increase in tip projection, but rather serves as a means of unifying the nasal tip and helping to control the final tip position.

Nasal tip angle:

Tip angle (TA) as described by Byrd and Hobar by dropping a perpendicular line from the Frankfurt Horizontal line through the alar crease junction (53). The angle is formed by intersecting another line from the alar crease junction to the most projecting part of the nasal tip. The ideal tip angle (TA) is 105 degrees for women and 100 degrees for men (54).

Columellar lobule angle:

Infratip lobule: The infratip lobule is the portion of the nose that is bounded superiorly by the tip-defining points and caudally by the columella. The infratip lobule is located in the center of the tip, adjacent to the supratip break and tip-defining features and counterbalancing them (55). The soft triangle and the apex of the nostril serve as its lateral boundaries. The infratip lobule projection is defined by a line drawn across the tip-defining points and the inferior extent of the lobule in an anteroposterior aspect. The apices of the nostrils should meet at the halfway of the infratip lobule in the ideal nose (55). The tip and the columellar lobular angle define the infratip lobule projection in the lateral view. The alar-columellar connection affects the projection visually. In the presence of a normal alar columellar connection, excessive infratip lobule projection indicates an issue with the length or width of the middle crus (56).

Lobule to nostril ratio:

When examining the opposite anomaly, large nostril/small lobule disproportion (57), Daniel discovered the optimal nostril/tip ratio to be 55:45 on the lateral view. A study Guyuron B et al. (58) also found that a favorable nostril/infratip lobule ratio ranges roughly in between 60:40 to 55:45. This was observed in the basilar view, similar to Daniel's observations.

The concept of usefulness isn't limited to nasal breathing enhancement. It also comprises the following elements:

- ¹/₄ Peripheral olfactory disturbances
- ¹/₄ Recurrent and chronic sinusitis
- ¹/₄ Middle ear ventilation problems
- ¹/₄ Rhinogenic headache
- ¹/₄ Poor vocal quality
- ¹/₄ Nasal ventilation problems

The most difficult surgeries in plastic facial surgery are functional aesthetic rhinoplasties. The rhinoplasty surgeon has a tremendous hurdle in and of itself. All of the above indications are logistically and technically viable to include without becoming buried in too many details, and we must answer the patient's desire to fix several problems in a single procedure (59).

Patients met with the physician, and those who were at high risk of developing body dysmorphic disorder were transferred to a clinical psychologist if they consented. Following that, the patient was re-evaluated at the rhinology clinic, and a care plan was agreed upon based on the clinical results and the clinical psychologist's opinion. Different races have different types of nasal shapes (60).

Character of nose in different races:

A. Character of Asian nose:

Each race has a distinctive nose shape. A narrow nose (leptorrhine) is common in Caucasians, a flat nose (platyrrhine) is common in African Americans, and Asians have traits that are halfway between the two races (mesorrhine). Anatomical considerations in Asian rhinoplasty include the following: (61)

- The dorsum of the nose is wide, low, and flat.
- The skin of the nose tip and supratip area has a thick dermis and a subcutaneous layer. There are also a lot of fibrofatty tissues in them. The sebaceous glands are well-developed as well.
- When viewed from the caudal side, the nostril is fanned out horizontally, resulting in a considerable space between the alar base on both sides.
- The nose tip is low, wide, and rounded (bulbous tip) because the alar cartilage is short and both sides are separated from the nose tip when viewed from the side.
- When viewed from the side, the nasolabial angle seems narrow and the ala is enormous and bent caudally.
- The anteriorly based nasal spine is hypoplastic.
- The alar cartilage is tiny and fragile, which makes suturing the alar cartilage alone difficult to project the nasal tip. It's also impossible for the alar cartilage to support the tip of the nose with the standard rhinoplasty technique used by Caucasians.
- Septal cartilage is very thin and, thus cannot be routinely used as an autogenous cartilage structural support graft.

B. Character of African nose:

Patients of African heritage are more likely to have a platyrrhine nose ('wide and flat'). It is characterized by the following characteristics:

- A low radix,
- A short, concave dorsum.
- An illusory widening of intercanthal distance,
- A bulbous, under projected tip
- Flared ala with round nostrils,
- Extremely thick skin.
- The nasofrontal angle is frequently as large as 130–140°.
- In these patients, rhinoplasty might result in hyperpigmentation or hypopigmentation, as well as hypertrophic scarring or keloids.

Sub-classifications of the platyrrhine nose have been described as a result of racial intermingling (62).

C. The character of Caucasian Nose:

- Thin-skinned nose
- Long columella
- Narrow alar base
- Overprojected nasal tip

In Caucasian noses, as well as in the Middle Eastern population, the tension nose deformity is frequent. Excess quadrangular cartilage generates a big dorsal bulge, a thin middle third of the nose, excess columella display, and sometimes a ptotic nasal tip in this malformation (61).

D. The character of Indian nose:

According to Sir Risley's anthropological classification, Dravidians, or individuals from Tamil Nadu and Andhra Pradesh, have broad noses, according to his assessment. Long and narrow noses are characteristic of Indo-Aryans in Punjab and Rajasthan. The noses of Aryo-Dravidians from Uttar Pradesh and Bihar are medium in size. The noses of Mongoloids living in the Himalayan region or the North East Frontier range from fine to broad (63). First, it should be noted that several authors have found differences in nasal morphology between North American Caucasians and Indians or South Asians (64). For example, Patil et al. found that Indian women have, on average, greater nasal width, nasal length, and a smaller nasolabial angle and tip projection. In addition, in our experience, there are certain common features of the Indian nose that differentiate it from the Caucasian nose: thicker skin, darker pigmentation, and weaker upper and lower lateral cartilages.

In addition, there are anecdotal differences between North and South Indians—for example; North Indians are commonly thought of as having less skin pigmentation than some South Indian populations. There are a few studies that lend credence to these perceived differences between the groups. In a study of 200 subjects, Prasanna et al. found that there was a statistically significant difference between the facial index (the ratio of facial height to facial width) of North and South Indians (65). Several other authors have investigated the soft-tissue and skeletal cephalometrics of North and South Indian populations and their results also show differences between these two groups (66-70). Without a formal meta-analysis, it is not possible to assign statistical significance to these differences. For example, comparing the reports of Kalha et al. (who studied 60 South Indian adults) and Jain and Kalra (who studied 60 North Indian adults) shows that North Indian women tend to have a smaller nasolabial angle (97.65 degrees) compared with South Indian women (103.47 degrees). The average female Caucasian angle falls in between these two, at 102 degrees.

Considered together, these studies point to a simple fact—there is no such thing as a "typical" Indian nose.

However, there are common regional variations that can help guide the rhinoplasty surgeon in his or her nasal analysis. Specifically, two broad subgroups can be defined based on this data.

The North Indian nose: The North Indian nose has features in common with the Middle Eastern and Persian nose with tip under rotation and over projection, dorsal hump, and wide bony vault.

The South Indian Nose: The South Indian nose has features in common with the African American nose, with an ill-defined under projected, over-rotated tip; lack of dorsal projection; and wide alar bases.

An anthropometric study involved 221 young, good-looking people of Indian parentage, aged 18–25 years, with no trauma or surgery to the nose. A reference scale was used to take standardized basal frontal and lateral pictures of the noses, and 11 standard anthropometric measurements of the nose were calculated (71).

Indian Male Nasal Parameters:

- ♦ Nasal length in males was 4.437 with SD 0.439 cm.
- ✤ Radix height 1.421 with SD 0.336 cm,
- Dorsal height 2.330 with SD 0.319 cm,
- ✤ Nasal tip projection 2.0790 with SD 0.272,
- ♦ Collumellar show 0.836 with SD 0.161,
- ♦ Nasal base 3.790 with SD 0.291 cm
- ♦ Inter-canthal distance 3.005 with SD 0.235 cm.
- ✤ Naso-frontal angle was 123.394 with SD 10.7835
- ✤ Naso–labial angle 100.619 with SD 15.480
- ♦ Naso-facial angle 41.721 with SD 5.1924
- ♦ Naso-mental angle was 124.483 with SD 5.1830

Indian Female Nasal Parameters:

- ♦ Nasal-length in females was 4.1338 with SD 0.4569 cm.
- ✤ Radix-height1.268 SD with 0.304 cm
- Dorsal-height 2.0488 with SD0.3046 cm
- ♦ Nasal-tip projection 1.9494 with SD 0.265
- ♦ Collumellar show 0.8045 with SD 0.204
- ♦ Nasal-base 3.5748 with SD 0.412 cm
- ✤ Inter-canthal distance 2.949 with SD 0.391 cm
- ✤ Naso-frontal angle was 134.3269 with SD8.8070
- ✤ Naso-labial angle 103.9878 with SD 12.659
- ♦ Naso-facial angle 37.6780 with SD.3062
- ♦ Naso-mental angle was 125.499 with SD 6.7892

Rhinoplasty outcome evaluation (ROE) score:

In clinical trials or to measure the success of medical procedures, self-reported outcomes are becoming increasingly regarded as significant results. In determining the success of facial plastic surgery, questionnaires designed to assess the quality of life and self-image are extremely useful because they standardize the information collected and allow for objective comparison of operations by assessing negatives and positives as well as improvements after rhinoplasty. (72-74).

History: There are a variety of patient-reported outcome measures that can be used to assess pre-and postoperative patient satisfaction and quality of life in rhinoplasty patients. These tools are divided into three categories: evaluating the aesthetic, functional, and combined outcomes (75). The facial appearance sorting test (FAST) can be used to evaluate rhinoplasty results. The Derriford Ford Appearance Scale (DAS-59) can be used to evaluate how appearance affects one's quality of life (76).

Alsarraf et al. were the first to develop and evaluate a questionnaire with high reliability, internal consistency, and validity for a variety of plastic operations, including rhinoplasty, in the year 2000 (77, 78). The Rhinoplasty Outcomes Evaluation (ROE) questionnaire provided for the analysis of qualitative factors such as social, emotional, and psychological aspects. Sena Esteves et al. verified the ROE

questionnaire with Portuguese respondents in 2013 (79). The ROE questionnaire, which consists of six questions and has been validated in Portuguese, was used (five about nose shape and one about nasal breathing). Each question was graded on a scale of 0 to 4, with 0 representing the most negative and 4 representing the most favorable. The sum of the scores was divided by 24 and multiplied by 100 to generate a value that ranged from 0 to 100. A lower score suggests that you are more dissatisfied. A difference between post-operative and pre-operative evaluations that are positive implies that the patient has improved after treatment.

Rhinoplasty outcomes evaluation (ROE)						
This questionnaire is designed to assist your surgeon in determining the best patient outcomes following rhinoplasty surgery. Your comments are confidential and may be used to refine surgical procedures for future patients. Please circle the number that best characterizes your current opinion regarding the following questions:						
1. How well do	you like the app	bearance of you	ır nose?			
	Not at all 0	Soemwhat 1	Moderately 2	Very much 3	Completely 4	
2. How well are	2. How well are you able to breathe through your nose?					
	Not at all 0	Soemwhat 1	Moderately 2	Very much 3	Completely 4	
3. How much do you feel your friends and loved ones like your nose?						
	Not at all 0	Soemwhat 1	Moderately 2	Very much 3	Completely 4	
4. Do you think your current nasal appearance limits you social or professional activities?						
	Always 0	Usually 1	Sometimes 2	Rarely 3	Never 4	
5. How confident are you that your nasal appearance is the best that it can be?						
	Not at all 0	Soemwhat 1	Moderately 2	Very much 3	Completely 4	
6. Would you like to surgically alter the appearance or function of your nose?						
	Definitely 0	Most likely 1	Possibly 2	Probably not 3	No 4	

AIM AND OBJECTIVES

AIM:

To compare preoperative and postoperative anthropometric measurements and subjective satisfaction in adult patients undergoing Primary Rhinoplasty in All India Institute of Medical Science, Jodhpur.

OBJECTIVES:

To measure anthropometric measurements of the nose based on an adult patient lifesize photograph and subjective satisfaction using Rhinoplasty Outcome Evaluation score (ROE) preoperatively and postoperatively.

RESEARCH QUESTION:

Was there an improvement in anthropometric measurements and subjective satisfaction of nose post-operatively in adult patients undergoing Primary Rhinoplasty?

RESEARCH HYPOTHESIS:

Null hypothesis

There was no improvement of nasal anthropometric measurements and subjective satisfaction in adult patients undergoing Primary Rhinoplasty.

Alternate hypothesis

There was an improvement in nasal anthropometric measurements and subjective satisfaction in an adult patient undergoing Primary Rhinoplasty.

METHODOLOGY

STUDY DESIGN: Prospective cohort study.

STUDY SETTING: The study was conducted in the Department of Otorhinolaryngology at All India Institute of Medical Sciences, Jodhpur (Rajasthan).

STUDY DURATION: December 2019 to December 2021.

SAMPLE FRAME: The proposed sample size was calculated based on a previous study was 41 (80) in December 2019, but we could do study on 20 patients operated for primary rhinoplasty due to the COVID-19 pandemic followed by mucormycosis.

INCLUSION CRITERIA:

- 1. Patients presented in the Department of Otorhinolaryngology at All India Institute of Medical Sciences, Jodhpur for primary rhinoplasty.
- 2. Patients aged 18 years or above.

EXCLUSION CRITERIA:

- 1. Previous surgical interventions on the nose and face.
- 2. Nasal deformities due to systemic diseases and congenital deformities.

STUDY POPULATION: The study was comprised of patients aged 18 years or above with cosmetic and/or functional disorders requiring primary rhinoplasty enrolled as per inclusion and exclusion criteria from the outpatient department of Otorhinolaryngology, All India Institute of Medical Sciences, Jodhpur. All patients single were operated on by a surgeon in the Department of Otorhinolaryngology. Informed consent was given. The study was commenced after approval of the Institutional Ethics committee (IEC) at All India Institute of Medical sciences, Jodhpur vide letter no. AIIMS/IEC/2019-20/983 dated 01/01/2020.

FUNDING:

No fund was received from any source for the completion of the study.

PREOPERATIVE WORKUP:

Real size Photography: The participants were seated comfortably in a chair in a relaxed anatomical position (neutral position of the head), and each patient's facial length was measured by measuring tape from vertex to chin and between the lateral most projected points of both pinna. The camera lens was oriented parallel to the subject's front face view. The neutral head posture was useful because it is easy to replicate, gives a natural facial orientation, and aids treatment planning.

The real-size photos were taken using a Nikon DSLR D70 camera mounted on a tripod at a distance of 1 meter between the subject and the lens. The person was instructed not to move while the images were being taken. A computer was used to transfer digital images, and the photography was analyzed immediately in the same sitting by Adobe Photoshop. Facial measurement was done by keeping the scale on the side during Photoshop to minimize the error and increase the accuracy of the measurement.
ANTHROPOMETRIC MEASUREMENT OF NASAL ANGLES:

Fig. 1: Naso-frontal angle



Fig. 2: Naso-labial angle







Fig. 4: Nasal tip angle





Fig. 6: Lobule to nostril ratio



STATISTICAL ANALYSIS

The collected data was analyzed using IBM SPSS software for Windows, Version 23.0 (Armonk, NY: IBM Corp).Data will be presented as mean, standard deviation, range (minimum and maximum), numbers and percentage, paired t test for the difference between two dependent means (pre compared to post compared) with p values less than or equal 0.05 will be considered as significant.

ETHICS APPROVAL

Approval to conduct this study was taken from the Institution Ethics Committee (IEC), AIIMS, Jodhpur (**IEC Reg. No.** – AIIMS/IEC/2019-20/983 dated 01/01/2020) attached in Appendix) Informed and written consent in a language the patient understands was obtained from the subjects before their participation in the study. There were reasonable ethical implications in this study.



RESULT:

In our study a comparison of ROE score was done on anthropometric analysis of nasal parameters of patients operated for primary rhinoplasty, preoperatively and 6 months postoperatively.

The collected data was analyzed using IBM SPSS software for Windows, Version 23.0 (Armonk, NY: IBM Corp). To find the significant difference between the bivariate samples in paired groups, the paired sample t-test was used. In the above statistical tool, a probability value of 0.05 was considered a significant level.

Table 1: Gender distribution

Gender distribution							
	Frequency	Percent					
Female	5	25.0					
Male	15	75.0					
Total	20	100.0					

The above table shows gender distribution among Female (25.0%) & Male (75.0%).





Results and Observations of ROE (Rhinoplasty outcome evaluation)

score:

To find the significant difference between the bivariate samples in Paired groups the pair sample t-test was used. In all the above statistical tools the probability value (p value) <0.05 is considered as significant level.

 Table 2: Comparison of Total ROE score preoperatively and 6 months

 postoperatively using paired sample t-test.

		Mean	N	SD	t-value	p-value	
Total ROE score	Preoperative	4.65	20	2.25		0.0005*	
	6 months postoperative	21.05	20	3.79	14.173		
* Statistical Significance at p < 0.05 level							



Figure 8

The above table shows comparison of total ROE score preoperatively and 6 months postoperatively. It was done using paired sample t-test. The mean value of the ROE score preoperatively and postoperatively was 4.65 and 21.05 respectively. The p-value was 0.0005 which was statistically significant.

Table 3: Comparison of ROE Score % preoperatively and 6 monthspostoperatively using paired sample t-test.

		Mean	Ν	SD	t-value	p-value	
ROE Score %	Preoperative	19.26	20	9.37			
	6 months postoperative	87.69	20	15.80	14.233	0.0005*	
*Statistical Significance at p < 0.05 level							





The above table shows the comparison of ROE score percentage preoperatively and at 6 months postoperatively. It was done using paired sample t-test. The mean score percentage preoperatively and 6 months postoperatively was 19.26% and 87.69 % respectively. The p-value was 0.0005 which was statistically significant.

 Table 4: Comparison of ROE score in female patients preoperatively and 6

 months postoperatively using paired sample t-test.

		Mean	Ν	SD	t-value	p-value	
Total ROE score	Preoperative	3.80	5	.45			
	6 months postoperative	23.00	5	1.41	39.192	0.0005*	
*Statistical Significance at p < 0.05 level							





The above table shows the comparison of ROE score of female patients preoperatively and 6 months postoperatively. It was done using paired sample t-test. The mean ROE scores in preoperatively and 6 months postoperatively was 3.80 and 23.00 respectively. The p-value was 0.0005 which was statistical significant.

 Table 5: Comparison of ROE Score % in female patients preoperatively and 6

 months postoperatively by using paired sample t-test.

		Mean	Ν	SD	t-value	p-value
	Preoperativ e	15.78	5	1.83		
ROE Score %	6 months postoperati ve	95.82	5	5.90	38.900	0.0005 *
* Statistical Significance at p < 0.05 level						



Figure 11

The above table shows the comparison of ROE score percentage of female patients preoperatively and 6 months postoperatively. It was done using paired sample t-test. The mean ROE score preoperatively and postoperatively was 15.78% and 95.82% respectively. The p-value was 0.0005 which was statistically significant.

Table 6: Comparison of ROE score in male patients preoperatively and 6 months postoperatively using paired sample t-test.

		Mean	Ν	SD	t-value	p-value	
ROE score	Preoperative	4.93	15	2.55			
	6 months postoperative	20.40	15	4.14	10.545	0.0005*	
*Statistical Significance at p < 0.05 level							



Figure 12

The above table shows the comparison of ROE score in male patients preoperatively and 6 months postoperatively. It was done using paired sample t-test. The mean ROE score preoperatively and postoperatively was 4.93 and 20.40 respectively. The pvalue was 0.0005 which was statistically significant.

Table 7: Comparison of ROE Score % preoperatively and 6 monthspostoperatively in male patients using paired sample t-test

		Mean	Ν	SD	t-value	p-value	
ROE Score %	Preoperative	20.41	15	10.61		3 0.0005 *	
	6 months postoperative	84.98	15	17.24	10.593		
* Statistical Significance at p < 0.05 level							





The above table shows the comparison of ROE score percentage in male patients preoperatively and 6 months postoperatively. It was done using paired sample t-test. The mean ROE score percentage preoperatively and postoperatively was 20.41%, and 84.98% respectively. The p-value was 0.0005 which was statistically significant.

Result of anthropometric analysis of nose:

 Table 8: Comparison of naso-frontal angle preoperatively and 6 months

 postoperatively in female patients using paired sample t-test

Variable	Treatment	Mean	N	SD	t-value	p-value	
Naso frontal angle	Preoperative	146.6	5	5.3		5 0.554 #	
	6 months postoperative	145.6	5	6.1	0.645		
# No Statistical Significance at p > 0.05 level							





The above table shows the comparison of naso-frontal angle in female patients preoperatively and at 6 months postoperatively. It was done using paired sample t-test. The mean naso-frontal angle preoperatively and postoperatively was 146.6 and 145.6 degrees respectively. The p-value was 0.554, which was not statistically significant.

 Table 9: Comparison of naso-labial angle in female patient preoperatively and 6

 months postoperatively using paired sample t-test.

Variable	Treatment	Mean	Ν	SD	t-value	p-value	
Naso Labial angle	Preoperative	81.8	5	15.4			
	6 months postoperative	96.2	5	11.7	2.310	0.082 #	
# No Statistical Significance at p > 0.05 level							





The above table shows the comparison of naso-labial angle in female patients preoperatively and 6 months postoperatively. It was done using paired sample t-test. The mean naso-labial angle preoperatively and postoperatively was 81.8 and 96.2 degrees respectively. The p-value was 0.082, which was statistically significant.

Table 10: Comparison of nasal tip angle in female patients preoperatively and 6months postoperatively using paired sample t-test

Variable	Treatment	Mean	Ν	SD	t-value	p-value	
Nasal tip angle	Preoperative	93.4	5	6.1			
	6 months postoperative	99.6	5	6.6	3.164	0.034 *	
* Statistical Significance at p < 0.05 level							





The above table shows the comparison of nasal tip angle in female patients preoperatively and 6 months postoperatively. It was done using paired sample t-test. The mean nasal tip angle preoperatively and postoperatively was 93.4 and 99.6 degrees respectively. The p-value was 0.034 which was statistical significance.

Table 11: Comparison of naso-facial angle in female patients preoperatively and6 months postoperatively using paired sample t-test

Variable	Treatment	Mean	Ν	SD	t-value	p-value	
Naso facial angle	Preoperative	27.6	5	4.3			
	6 months postoperative	30.2	5	4.4	2.152	0.098 #	
# No Statistical Significance at p > 0.05 level							



Figure 17

The above table shows the comparison of naso-facial angle in female patients preoperatively and 6 months postoperatively. It was done using paired sample t-test. The mean naso-facial angle preoperatively and postoperatively was 27.6 degrees and 30.2 degrees respectively. The p-value was 0.098, which was not statistically significant.

Table 12: Comparison of columellar lobule angle in female patientspreoperatively and 6 months postoperatively by using paired sample t-test

Variable	Treatment	Mean	Ν	SD	t-value	p-value	
Columellar lobule angle	Preoperative	39.2	5	15.0	4 004	0.004.#	
	6 months postoperative	33.0	5	6.0	1.024	0.364 #	
# No Statistical Significance at p > 0.05 level							



Figure 18

The above table shows the comparison of columellar lobule angle in female patients preoperatively and 6 months postoperatively. It was done using paired sample t-test. The mean columellar lobule angle preoperatively and postoperatively was 39.2 and 33.0 degrees respectively. The p-value was 0.364, which was not statistically significant.

 Table 13: Comparison of Lobule to nostril ration in female patients

 preoperatively and 6 months postoperatively using paired sample t-test

Variable	Treatment	Mean	Ν	SD	t-value	p-value			
Lobule to nostril ration	Preoperative	1.09	4	0.48					
	6 months postoperative	1.16	4	0.14	0.243	0.824 #			
# No Statistical Significance at p > 0.05 level									



Figure 19

The above table shows the comparison of lobule to nostril ratio in female patients preoperatively and 6 months postoperatively. It was done using paired sample t-test. The mean lobule to nostril ratio preoperatively and postoperatively was 1.09 and 1.16 respectively. The p-value was 0.824, which was not statistically significant.

Table 14: Comparison of naso-frontal angle in male patients preoperatively and6 months postoperatively using paired sample t-test

Variable	Treatment	Mean	Ν	SD	t-value	p-value			
Naso frontal angle	Preoperative	135.3	15	13.6					
	6 months postoperative	139.2	15	9.0	2.547	0.023 *			
* Statistical Significance at p < 0.05 level									



Figure 20

The above table shows the comparison of the naso-frontal angle in male patients preoperatively and at 6 months postoperatively. It was done using paired sample t-test. The mean naso-frontal angle preoperatively and postoperatively was 135.3 degrees and 139.2 degrees respectively. The p-value was 0.023, which was statistically significant.

Table 15: Comparison of naso-labial angle in male patients preoperatively and 6months postoperatively using paired sample t-test

Variable	Treatment	Mean	Ν	SD	t-value	p-value				
Naso Labial angle	Preoperative	85.2	15	9.2		0.014 *				
	6 months postoperative	89.6	15	6.7	2.792					
* Statistical Significance at p < 0.05 level										



Figure 21

The above table shows the comparison of the naso-labial angle in male patients preoperatively and 6 months postoperatively. It was done using paired sample t-test. The mean naso-labial angle preoperatively and postoperatively was 85.2 degrees and 89.6 degrees respectively. The p-value was 0.014, which was statistically significant.

 Table 16: Comparison of nasal tip angle in male patients preoperatively and 6

 months postoperatively using paired sample t-test

Variable	Treatment	Mean	Ν	SD	t-value	p-value				
Nasal tip angle	Preoperative	92.1	15	7.2						
	6 months postoperative	94.0	15	4.2	1.227	0.240 #				
# No Statistical Significance at p > 0.05 level										



Figure 22

The above table shows the comparison of the nasal tip angle in male patients preoperatively and 6 months postoperatively. It was done using paired sample t-test. The mean nasal tip angle preoperatively and postoperatively was 92.1 degrees and 94.0 degrees respectively. The p-value was 0.240, which was not statistically significant.

Table 17: Comparison of naso-facial angle in male patients preoperatively and 6 months postoperatively using paired sample t-test

Variable	Treatment	Mean	Ν	SD	t-value	p-value			
Naso facial angle	Preoperative	30.5	15	5.3		0.890 #			
	6 months postoperative	30.6	15	5.2	0.141				
# No Statistical Significance at p > 0.05 level									



Figure 23

The above table shows the comparison of naso-facial angle in male patients preoperatively and 6 months postoperatively. It was done using paired sample t-test. The mean naso-facial angle preoperatively and postoperatively was 30.5 degrees and 30.6 degrees respectively. The p-value was 0.890, which was not statistically significant.

 Table 18: Comparison of columellar lobule angle in male patients preoperatively

 and 6 months postoperatively paired sample t-test by using paired sample t-test

Variable	Treatment	Mean	Ν	SD	t-value	p-value			
Columellar lobule angle	Preoperative	30.5	15	3.2		0.018 *			
	6 months postoperative	28.7	15	4.6	2.685				
* Statistical Significance at p < 0.05 level									



Figure 24

The above table shows the comparison of columellar lobule angle in male patients preoperatively and 6 months postoperatively. It was done using paired sample t-test. The mean columellar lobule angle preoperatively and postoperatively was 30.5 degrees and 28.7 degrees respectively. The p-value was 0.018, which was statistically significant.

Table 19: Comparison of lobule to nostril ration in male patients preoperativelyand 6 months postoperatively using paired sample t-test

Variable	Treatment	Mean	Ν	SD	t-value	p-value
Lobule to nostril ration	Preoperative	1.2	15	0.4		0.437 #
	6 months postoperative	1.1	15	0.2	0.800	
	# No S	tatistical Sig	nificance at	p > 0.05 leve	əl	



Figure 25

The above table shows the comparison of lobule to nostril ratio in male patients preoperatively and 6 months postoperatively. It was done using paired sample t-test. The mean lobule to nostril ratio preoperatively and postoperatively was 1.2 and 1.1. The p-value was 0.437 which was not statistically significant.

Table 20: Descriptive Statistics of Female:

Naso- Fronral	Ν		Magin	Madian	0.0	Denne	N dia iany san	Maxim
Angle	Valid	Missing	Mean	Median	5.D	Range	winimum	waximum
Pre op	5	0	146.6	150.0	5.3	12.0	138.0	150.0
Post op 1 month	5	0	145.6	149.0	5.1	10.0	140.0	150.0
Post Op 3 months	3	2	142.7	140.0	6.4	12.0	138.0	150.0
Post op 6 months	5	0	145.6	150.0	6.1	12.0	138.0	150.0

Naso- labial angle	Ν		Maan	Madian	<u>е р</u>	Dongo	Minimum	Maximum
	Valid	Missing	wear	Median	5.D	Range	wiiniiniuni	IVIAXIITIUTTI
Pre op	5	0	81.8	83.0	15.4	39.0	57.0	96.0
Post op 1 month	5	0	96.6	95.0	11.4	29.0	87.0	116.0
Post Op 3 months	3	2	102.0	97.0	12.3	23.0	93.0	116.0
Post op 6 months	5	0	96.2	93.0	11.7	30.0	86.0	116.0

Nasal tip angle	Ν		Maan	Madian	<u>е п</u>	Dongo	Minimum	Maximum
	Valid	Missing	Wearr	weatan	3.0	Range	wiiminum	IVIAXIMUM
Pre op	5	0	93.4	94.0	6.1	15.0	85.0	100.0
Post op 1 month	5	0	100.4	101.0	6.1	15.0	95.0	110.0
Post Op 3 months	3	2	103.3	100.0	5.8	10.0	100.0	110.0
Post op 6 months	5	0	99.6	100.0	6.6	17.0	93.0	110.0

Naso- Facial Angle	Ν		Moon	Madian	8 D	Pango	Minimum	Maximum
	Valid	Missing	wear	Wealan	3.0	Kange	Winning	
Pre op	5	0	27.6	25.0	4.3	10.0	25.0	35.0
Post op 1 month	5	0	32.4	35.0	3.6	7	28	35
Post Op 3 months	3	2	32.3	34.0	3.8	7.0	28.0	35.0
Post op 6 months	5	0	30.2	28.0	4.4	9.0	26.0	35.0

Columella r Lobule Angle	Ν		Moon	Madian	8 0	Bongo	Minimum	Maximum
	Valid	Missing	Wear	weatan	3.0	Range	wiiriirriurri	IVIAAIITTUTT
Pre op	5	0	39.2	35.0	15.0	37.0	28.0	65.0
Post op 1 month	5	0	32.0	35.0	8.0	19.0	19.0	38.0
Post Op 3 months	3	2	30.7	30.0	7.0	14.0	24.0	38.0
Post op 6 months	5	0	33.0	35.0	6.0	14.0	24.0	38.0

Lobule to	Ν		Maan	Median	S.D	Bongo	Minimu	Maximum
ratio	Valid	Missing	wear	Weulan	3.0	Range	m	Maximum
Pre op	4	1	1.09	1.1	0.5	1.17	.50	1.67
Post op 1 month	4	1	1.2	1.2	0.2	.36	1.14	1.50
Post op 6 months	3	2	1.11	1.0	0.19	0.33	1.00	1.33
Post op 6 months	4	1	1.16	1.2	0.1	.33	1.00	1.33

Table 21: Descriptive Statistics of Male

Naso-	Ν		Moon	Madian	<u>е п</u>	Panga	Minimum	Movimum	
Angle	Valid	Missing	Mean	weatan	3.0	Range	wiimiimum		
Pre op	15	0	135.3	137.0	13.6	49.0	103.0	152.0	
Post op 1 month	14	1	137.1	136.0	9.0	29.0	121.0	150.0	
Post Op 3 months	7	8	136.9	135.0	8.7	24.0	124.0	148.0	
Post op 6 months	15	0	139.2	138.0	9.0	30.0	122.0	152.0	

Naso-	Ν		Maan	Madian	8.0	Range	Minimum	Maximum	
angle	Valid	Missing	Mean	weatan	3.0	Range	wiiniiniuni		
Pre op	15	0	85.2	87.0	9.2	31.0	69.0	100.0	
Post op 1 month	14	1	90.4	90.5	4.8	17.0	81.0	98.0	
Post Op 3 months	7	8	88.6	88.0	7.3	22.0	78.0	100.0	
Post op 6 months	15	0	89.6	89.0	6.7	25.0	75.0	100.0	

Nasal tip	Ν		Moon	Modian	<u>е п</u>	Bango	Minimum	Maximum
angle	Valid	Missing	Missing Mean Median S.D Range		winning	Maximum		
Pre op	15	0	92.1	90.0	7.2	25.0	82.0	107.0
Post op 1 month	14	1	95.3	95.0	4.1	13.0	90.0	103.0
Post Op 3 months	7	8	94.3	92.0	4.4	10.0	90.0	100.0
Post op 6 months	15	0	94.0	93.0	4.2	15.0	87.0	102.0

Naso-	N		Moon	Madian	80	Pongo	Minimum	Movimum	
Angle	Valid	Missing	wear	weatan	3.0	Range	wiiriirriurri		
Pre op	15	0	30.5	30.0	5.3	19.0	23.0	42.0	
Post op 1 month	14	1	31.7	30.5	5.3	17	23	40	
Post Op 3 months	7	8	32.0	30.0	4.0	12.0	28.0	40.0	
Post op 6 months	15	0	30.6	30.0	5.2	17.0	23.0	40.0	

Columella	Ν		Maan	Madian	<u> </u>	Dongo	Minimum	Movimum	
Angle	Valid	Missing	Mean	n Median S.D Range		Range	winimum	IVIAAIITTUTT	
Pre op	15	0	30.5	30.0	3.2	12.0	26.0	38.0	
Post op 1 month	14	1	27.3	28.0	4.4	18.0	20.0	38.0	
Post Op 3 months	7	8	28.4	28.0	5.5	18.0	20.0	38.0	
Post op 6 months	15	0	28.7	30.0	4.6	18.0	20.0	38.0	

Lobule to	Ν		Moon	Modion	8.0	Bongo	Minimum	Movimum	
ratio	Valid	Missing	Mean Median Missing		3.0	Range	wiiniiniuni	Maximum	
Pre op	15	0	1.2	1.0	0.4	1.29	.71	2.00	
Post op 1 month	14	1	1.2	1.1	0.2	.75	.75	1.50	
Post op 3 months	7	8	1.2	1.3	0.2	0.60	1.00	1.60	
Post op 6 months	15	0	1.1	1.0	0.2	.75	.75	1.50	

Table 22: RHINOPLASTY OUTCOME EVALUATION SCORE BEFORE

SURGERY:

PATIENT	How much do you like the appearance of your nose? : Absolutely no (0)/ A little (1)/More or less (2)/Very much (3)/Absolutel y yes (4)	How much can you breathe through your nose? Absolutely no (0)/ A little (1)/More or less (2)/Very much (3)/Absolut ely yes (4)	How much do you think your friends and those closed to you like your nose? Absolutely no (0)/ A little (1)/More or less (2)/Very much (3)/Absolut ely yes (4)	Do you think the appearance of your nose limits your social or professional activities? Absolutely no (0)/ A little (1)/More or less (2)/Very much (3)/Absolutely yes (4)	How confident are you that your nose has the best possible appearance ? Absolutely no (0)/ A little (1)/More or less (2)/Very much (3)/Absolut ely yes (4)	Would you like to surgically change the appearance or function of the nose? : Certainly yes (0)/Very likely yes (1)/Possibly yes (2)/Probably no (3)/Certainly no (4)	Total	Percent age.
Α	1	0	1	0	1	0	03/24	12.5
В	0	2	0	1	1	0	04/24	16.6
С	0	1	1	1	1	0	04/24	16.6
D	2	0	2	2	0	0	06/24	25
E	0	4	0	0	0	0	04/24	16.6
F	0	4	0	0	1	0	05/24	20
G	0	0	0	0	1	0	01/24	4.16
н	0	2	1	0	1	0	04/24	16.6
I	2	3	2	2	2	0	11/24	45.8
J	0	2	0	0	0	0	02/24	8.33
к	0	1	1	2	0	0	04/24	16.6
L	1	0	2	2	1	0	06/24	25
м	1	0	2	1	2	1	07/24	29.1
N	0	2	0	1	1	0	04/24	16.6
0	0	0	1	0	1	0	02/24	8.33
Р	1	1	2	2	1	0	07/24	29.1
Q	0	1	2	1	1	0	05/24	20
R	0	2	0	0	1	0	03/24	12.5
S	2	0	2	2	1	0	07/24	29.1
т	0	4	0	0	0	0	04/24	16.6

Table 23: RHINOPLASTY OUTCOME EVALUATION SCORE AFTER

SURGERY:

PATIEN T NAME	How much do you like the appearance of your nose? : Absolutely no (0)/ A little (1)/More or less (2)/Very much (3)/Absolutel y yes (4)	How much can you breathe through your nose? Absolutely no (0)/ A little (1)/More or less (2)/Very much (3)/Absolut ely yes (4)	How much do you think your friends and those closed to you like your nose? Absolutely no (0)/ A little (1)/More or less (2)/Very much (3)/Absolutely yes (4)	Do you think the appearance of your nose limits your social or professional activities? Absolutely no (0)/ A little (1)/More or less (2)/Very much (3)/Absolutel y yes (4)	How confident are you that your nose has the best possible appearance? Absolutely no (0)/ A little (1)/More or less (2)/Very much (3)/Absolutel y yes (4)	Would you like to surgically change the appearance or function of the nose? : Certainly yes (0)/Very likely yes (1)/Possibly yes (2)/Probably no (3)/Certainly no (4)	Total	Percent age.
Α	3	4	3	4	3	4	21/24	87.5
В	4	3	3	4	4	3	21/24	87.5
С	4	4	4	4	4	4	24/24	100
D	3	4	3	3	4	3	20/24	83.33
E	4	4	4	4	4	4	24/24	100
F	2	4	0	0	2	2	10/24	41.66
G	4	4	4	4	4	4	24/24	100
н	3	4	4	4	4	4	23/24	95.8
I	2	3	2	2	3	3	17/24	70.8
J	4	3	3	4	4	4	22/24	91.6
к	3	4	4	4	4	3	22/24	91.6
L	3	3	2	2	3	1	14/24	58.3
м	3	4	2	3	3	4	19/24	79.1
N	4	4	4	4	4	4	24/24	100
0	3	4	4	4	3	3	21/24	87.5
Р	4	4	4	4	4	4	24/24	100
Q	4	4	4	4	4	4	24/24	100
R	4	4	4	4	4	4	24/24	100
S	3	4	3	3	3	3	19/24	79.1
т	4	4	4	4	4	4	24/24	100

Summary:

Out of total patients 75% were male and 25% were female.

Comparison of ROE scores overall:

- The mean value of the ROE score preoperatively and postoperatively was 4.65 and 21.05 respectively. The p-value was 0.0005 which was statistically significant.
- 2. The mean score percentage preoperatively and 6 months postoperatively was 19.26% and 87.69 % respectively. The p-value was 0.0005 which was statistically significant.

Comparison of ROE scores in females:

- 1. The mean ROE score preoperatively and postoperatively was 15.78% and 95.82% respectively. The p-value was 0.0005 which was statistically significant.
- 2. Preoperatively, the mean score percentage was 15.78% and 6 months postoperatively was 95.82%. The p-value was 0.0005, which was statistically significant.

Comparison of ROE scores in male patients.

- 1. The mean ROE score preoperatively and postoperatively was 4.93 and 20.40 respectively. The p-value was 0.0005 which was statistically significant.
- 2. The mean ROE score percentage preoperatively and postoperatively was 20.41%, and 84.98% respectively. The p-value was 0.0005 which was statistically significant.

The result of anthropometric analysis of the nose:

Comparison in female patients:

Naso-frontal angle: The mean naso-frontal angle preoperatively and postoperatively was 146.6 and 145.6 degrees respectively. The p-value was 0.554, which was not statistically significant.

Naso-labial angle: The mean naso-labial angle preoperatively and postoperatively was 81.8 and 96.2 degrees respectively. The p-value was 0.082, which was statistically significant.

Nasal tip angle: The mean nasal tip angle preoperatively and postoperatively was 93.4 and 99.6 degrees respectively. The p-value was 0.034 which was statistical significant.

Naso-facial angle: The mean naso-facial angle preoperatively and postoperatively was 27.6 degrees and 30.2 degrees respectively. The p-value was 0.098, which was not statistically significant.

Columellar lobule angle: The mean columellar lobule angle preoperatively and postoperatively was 39.2 and 33.0 degrees respectively. The p-value was 0.364, which was not statistically significant.

Lobule to nostril ratio: The mean lobule to nostril ratio preoperatively and postoperatively was 1.09 and 1.16 respectively. The p-value was 0.824, which was not statistically significant.

Comparison in male patients:

Naso-frontal angle: It was done using paired sample t-test. The mean naso-frontal angle preoperatively and postoperatively was 135.3 degrees and 139.2 degrees respectively. The p-value was 0.023, which was statistically significant.

Naso-labial angle: It was done using paired sample t-test. The mean naso-labial angle preoperatively and postoperatively was 85.2 degrees and 89.6 degrees respectively. The p-value was 0.014, which was statistically significant.

Nasal tip angle: The mean nasal tip angle preoperatively and postoperatively was 92.1 degrees and 94.0 degrees respectively. The p-value was 0.240, which was not statistically significant.

Naso-facial angle: The mean naso-facial angle preoperatively and postoperatively was 30.5 degrees and 30.6 degrees respectively. The p-value was 0.890, which was not statistically significant.

Columellar lobule angle: The mean columellar lobule angle preoperatively and postoperatively was 30.5 degrees and 28.7 degrees respectively. The p-value was 0.018, which was statistically significant.

Lobule to nostril ratio: The mean lobule to nostril ratio preoperatively and postoperatively was 1.2 and 1.1. The p-value was 0.437 which was not statistically significant.

DISCUSSION
Significant changes in facial parameters and proportions were observed six months following rhinoplasty, and their satisfaction with their nasal shape increased as well (81). Aesthetics are defined by symmetrical, balanced and harmonious facial proportions. The shape of the nose reveals information about race, ethnicity, age and gender. The size, shape, and proportions of the nose provide a visual basis for inferring the personality of a person. Furthermore, it is a crucial component of a natural and aesthetically beautiful human face (82). Beauty and its concepts are defined differently depending on ethnicity.

The anthropometric analysis is a method that uses certain landmarks identified in relation to anatomical prominences to produce the most trustworthy comparison of body forms. For anthropometric measurements of the nose, real sized photographs of the face are a simple and effective method. The anthropometric analysis aids in the improvement of corrective surgical plans.

Recently, many people have expressed interest in rhinoplasty procedures to alter the form of their noses and enhance the beauty of their faces. According to the world rhinoplasty statistics for 2017, India ranked 7th in the world for the most rhinoplasty procedures performed, with 878,180 rhinoplasties performed, accounting for 3.7 percent of the global population (83).

A successful rhinoplasty outcome necessitates meticulous and accurate preoperative planning. This can be accomplished by a detailed preoperative analysis and intricate designing of the procedure in mind. Any rhinoplasty surgeon must be aware of the racial and ethnic variances in nasal architecture between male and female members of a given group.

India is a vast country with a diverse cultural landscape. There is no comprehensive study that covers the entire Indian nose with its variations. As a result, Indians cannot be held to the same European and American standards. In the anthropometry of the nose, we predicted regional variations. As a result, the sample size was chosen in such a way that it included people from all four zones: north, south, east, and west.

According to anthropologists, different nasal shapes and sizes are attributable to the evolutionary adaptability of the nose to the local climate. According to Negus,

populations that lived in dry environments had wide, protruding external noses, nostrils that point downward and skeletal apertures that are narrower (84). These properties are hypothesized to cause turbulence in nasal airflow, allowing for more filtration and humidification of the air within the nasal passages. Here in our study, we were mainly dealing with the population of a dry environment typical of northwestern India. These features had been found in our study population too. As a result, the purpose of our study was to ensure that the physiological function of the nose was not disrupted.

Naso-frontal angle:

It has been seen that males have a narrower naso-frontal angle than females, which could be attributable to their projecting foreheads. The researchers conducted an anthropometric study with 221 young, good-looking Indian males and females aged 18–25 years old with no history of previous surgery or trauma to the nose. They discovered that the nasal angle of the female was 134.3269 with standard deviation of 8.8070 and that of the male was 123.394 with standard deviation of 10.783 (71). This proved that the female had a more obtuse angle compared to the male in the Indian population.

The people of the Himalayan area have the broadest naso-frontal angle which could be due to an overall flatter nose in the population of the region (85).

In our study, mainly patients with saddle nose deformity had a decreased naso-frontal angle, while the rest of the population had no significant change in the angle. In our study, it has also been seen that males have a more acute pre-op naso-frontal angle, i.e., (135.3 + -13.6) and females have a more obtuse naso-frontal angle, i.e., (146.6 + -5.2). The mean 6-month post-operative naso-frontal angle in male was (139.2 + -9), which was comparable to the value of 138.54, as found in the study done by Mehta et al. on anthropometric analysis of the Indian nose (85). The mean 6-month post-operative naso-frontal angle in our study was 0.023 for male patients, which was statistically significant. The p-value was 0.554 for female patients, which was not statistically significant.

Naso-labial angle:

Due to the higher forward angulations of the upper lip in men, the naso-labial angle may be more acute. The naso-labial angle was shortest in the Western Indian population and widest in the populations of the Central and Himalayan regions (87). The downward tip projection could be the reason for the small angle in the Western Indian subjects. According to Armijo et al. the ideal naso-labial angle in male patients and female patients were (93.4–98.50) and (95.5–100) respectively (86).

Nikhil Mehta et al. did an anthropometric nasal analysis of the Indian nose, in which they concluded that the mean naso-labial angle was 104, with females having a larger naso-labial angle than males. Due to higher forward angulation of the upper lip in men, the naso-labial angle could be more acute (85).

In general, the ideal naso-labial angle for an average good-looking male is 100.6. The mean naso-labial angle in male patients in our study, preoperatively and postoperatively was 85.2 degrees and 89.6 degrees respectively. The increased mean naso-labial angle post-operatively, was closer to the ideal. The p-value was 0.014, which was statistically significant.

The ideal naso-labial angle for an average good-looking female is 103.9. The mean naso-labial angle preoperatively and postoperatively was 81.8 and 96.2 degrees respectively, which was close to the ideal. The p-value was 0.082, which was statistically significant.

Naso-facial angle:

In the study by Nikhil Mehta et al., the average naso-facial angle was 35.960. Males exhibited a greater nasal dorsum inclination, indicating a more projecting nasal dorsum. The Indian subcontinent had the highest naso-facial angle of the several locations analyzed, while the Himalayan region had the lowest. This evidence supports our prior findings that the Himalayans have flatter noses and South Indians have more projecting noses (85).

The mean naso-facial angle preoperatively and postoperatively was 30.5 degrees and 30.6 degrees respectively in male patients. There was no significant change in the

mean naso-facial angle after surgery (p-value = 0.890). The ideal mean naso-facial angle for Indian males is 41 degrees with a standard deviation of 5.1. Hence on analysis, the post-operative result did not reach the desired value.

The ideal naso-facial angle for Indian females is 37.67 degrees with a standard deviation of 0.3. The mean naso-facial angle preoperatively and postoperatively was 27.6 degrees and 30.2 degrees respectively. The p-value was 0.098, which was not statistically significant.

Lobule to nostril ratio:

Daniel discovered the optimal nostril/tip ratio to be 55:45 (57). A study Guyuron B et al. (58) also found that a favorable nostril/infratip lobule ratio ranges roughly in between 60:40 to 55:45. This was observed in the basilar view, similar to Daniel's observations. However, these measurements were done among the leptorrhine group of population.

Nikhil Mehta et al. conducted a descriptive cross-sectional epidemiological investigation on 1000 Indians, and found that the nasal profiles differed throughout the five regions of the country. The longest (52.69 mm nasal height) and narrowest (35.01 mm width) noses were seen in North Indians, similar to a leptorrhine nose with Caucasoid traits. The noses of South Indian population, were the widest (38.66 mm), while those of Himalayan individuals were the shortest (nasal height = 47.2 mm). On an average, Indians have a mesorrhine nose, compared to the leptorrhine noses in Caucasians and Orientals and platyrrhine noses in Africans (85).

In our study, we were dealing with mesorrhine noses on average. Pre-operatively and post-operatively nostril to lobule ratio was 1:2 and 1:1 respectively in all male patients. So there was a decrease in the mean ratio of lobule to nostril post-operatively which was more towards leptorrhine but it was not statistically significant (p-value = 0.437).

In our study, among the female patients, the mean lobule to nostril ratio preoperatively and postoperatively was 1.09:1 and 1.16:1 respectively. Hence, the

mean lobule to nostril ratio increased and was not statistically significant (p-value = 0.824).

Nasal tip angle:

The ideal tip angle (TA) is 105 degrees for women and 100 degrees for men (54) as mentioned by Daniel RK in his book Rhinoplasty: Aesthetic Plastic Surgery. However, it was mentioned as ideal for the leptorrhine nose but not for the Indian subcontinent. On average, Indians noses are more similar to the mesorrhine type. However, in our study the patients expressed a stronger desire for the leptorrhine type of nose.

In the male patients, the mean nasal tip angle preoperatively and postoperatively was 92.1 degrees and 94.0 degrees respectively. So there was an increase in the mean nasal tip angle postoperatively, which was more towards the value of the leptorrhine type (the ideal is 100 degrees for men). Here the p-value was 0.240, which was not statistically significant.

In the female patients, the mean nasal tip angle preoperatively and postoperatively was 93.4 and 99.6 degrees respectively. There was an increased mean nasal tip angle, which also goes towards the value of the leptorrhine type (the ideal is 105 degrees for women). The p-value was 0.034 which was statistical significance.

Columellar lobule angle:

The confluence of the columella and the infratip lobule forms the columellar lobular angle. In females (90), the angle ranges from 30 to 45 degrees.

In our study, the mean columellar lobule angle preoperatively and postoperatively was 30.5 degrees and 28.7 degrees respectively in male patients. The p-value was 0.018, which was statistically significant.

In the female patients, the mean columellar lobule angle preoperatively and postoperatively was 39.2 and 33.0 degrees respectively. The value was within the normal range for leptorrhine patients. The p-value was 0.364, which was not statistically significant.

However, there was complete patient satisfaction, with no complaints from the patients regarding their nasal tip shape postoperatively.

Rhinoplasty outcome evaluation score:

One study found that individuals with lower socioeconomic status had lower surgical expectations. In addition, they required fewer counseling sessions. On the other hand, patients who had more information and awareness of the operation also had higher expectations from the surgery, necessitating multiple meetings with the surgeon to gain a better understanding of the operation (87). In that study, the mean ROE preoperative score was 30.5 and the mean postoperative score was 79.5, indicating a 49-point gain following surgery. Females had a slightly higher satisfaction level with the surgery than males, according to the study (females 80.9, males 78.2).

Similarly, in our study, the mean pre-operative ROE score was 19.25 and the postoperative score was 87.68, indicating a 68.43 point gain following surgery. The females had a somewhat higher satisfaction score with the surgery (95.82) as compared to the males (84.96). These results are in accordance with those of Khan et al., who found that females are more satisfied (87) as well as Khansa et al., who found that males are less satisfied (88). According to another assessment of male rhinoplasties (89), males had non-specific complaints and poorer knowledge of their abnormality than females.

The subjective assessments of all the 20 patients, at 6 month post-operative period, were done by the rhinoplasty outcome questanniore method. Among them, 17 patients had excellent satisfaction, 2 patients had good satisfaction and 1 patient had acceptable satisfaction. The grades of satisfaction were taken as 5.0% (Acceptable), 10.0% (Good) and 85.0% (Excellent).

STRENGTH AND LIMITATION

STRENGTHS:

- 1. All the patients were followed up to six months after surgery.
- 2. All the surgeries were done by a single surgeon.
- 3. All the pre-op and post-op photographs were taken and anthropometric measurements were done by a single person.

LIMITATIONS:

- 1. Few patients did not turn off for follow up at 1-month and 3-month postoperative. Hence, the comparison could not accurately evaluate the difference between 1 month and 3 months postoperatively.
- 2. Each patient who was operated had a unique deformity, not all nasal anthropometric measurements. These all patient were operated in such a way that every nasal anthropometric measurement became closer to the ideal for an Indian average good-looking person.

CONCLUSION

In our study, majority of the patients were male. In our study, most of the patients were young and had a history of trauma. Few patients also underwent primary rhinoplasty as per requirement for medical fitness in require for medical army recruitment.

Patients belonging to lower socioeconomic background had less surgical expectations and were highly satisfied with the outcomes. Patients, who knew more about the procedure and were more conscious of it, had higher expectations. According to our research, females had higher satisfaction than male after primary rhinoplasty.

According to the Rhinoplasty outcome evaluation score, 17 patients had excellent satisfaction, 2 patients had good satisfaction and 1 patient had acceptable satisfaction.

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ANNEXURES

ANNEXURE- A: INFORMED CONSENT FORM (ENGLISH)

Title of the project: Comparison of pre and postoperative nasal anthropometric measurements and subjective assessments in adult patients undergoing Primary Rhinoplasty.

Name of Thesis Candidate: Dr. Abir Chowdhury

Name of Chief Guide: Dr. Kapil Soni Tel. No. 9468042462

Patient/Volunteer Identification No. :

I, ______ S/o or D/o ______ R/o

give my full, free, voluntary consent to be a part of the study "______", the procedure and nature of which has been explained to me in my own language to my full satisfaction. I confirm that I have had the opportunity to ask questions. I understand that my participation is voluntary and am aware of my right to opt out of the study at any time without giving any reason. I understand that the information collected about me and any of my medical records may be looked at by responsible individual from ______(Company Name) or from regulatory authorities. I give permission for these individuals to have access to my records.

Date: _		 	
Place:			

Signature/Left thumb

impression

This to certify that the above consent has been obtained in my presence.

Date:					
Place:	Signature of Principal				
Investigator					
1. Witness 1	Witness 2				
Signature	Signature				
Name:	Name:				
Address:	Address:				

Informed Consent Form to Participate in a Research Study:

Title: Comparison of pre and postoperative nasal anthropometric measurements and subjective assessments in adult patients undergoing Primary Rhinoplasty

	Subject's Initials:	Subject's Name:
	Date of Birth / Age:	
	Please initial	
	Box (Subject)	
(i) oppo	I confirm that I have read and und Consent Form dated ortunity to ask questions.	erstood the information and []_2019/2021 for the above study and have had the
(ii)	I understand that my participation I am free to withdraw at any tim care or legal rights being affected.	in the study is voluntary and that [] e, without giving any reason, without my Medical
(iii)	I understand that the investigator of Will not need my permission to	of the research and the Ethics Committee [] look at my health records both in respect of the

- (ii] ect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial. I agree to this access. However, I understand that my identity will not be revealed in any information released to third parties or published.
- (iv) I agree not to restrict the use of any data or results that arise from this study[] Provided such a use is only for scientific purpose(s).

(v) I agree to take part in the above study	у. []
Signature (or Thumb impression) of the	Subject/Legally Authorized Representative
	Date: / /
Subject's name (printed)	
Signature (or Thumb impression) of the	caregiver
	Date://
Caregiver's name (printed)	
Name of the subject's legally authorized	representative (if LAR required)
Signature of the Investigator:	Date ://
Study Investigator's Name:	
Signature of Impartial witness	Date://
Name of Impartial Witness:	

ANNEXURE- B: INFORMED CONSENT FORM (HINDI)

सूचित सहमति फार्मः

परियोजना का	शीर्षक: प्राथ मव	<mark>क राइनोप्लास्</mark> टी के	दौर से गुज	र रहे वयस्व	ठ रो गयों में	ं प्री और
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में समझता हं व	ु क मेरी भागीदारी	स्वैच्छिक है और बि	ोना कसी कार	एग के कसी	भी समय अ	ध्ययन से
बाहर निकलने वे	न मेरे अ धकार से	अवगत हं।				
में समझता हं	क मेरे और म	नेरे कसी भी में ड	कल रिकॉर्ड वे	h बारे में प	खत्रित जान	कारी को
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निष्पक्ष साक्षी व	का नामः					

# **ANNEXURE- C: PATIENT INFORMATION SHEET (ENGLISH)**

**Title:** Comparison of pre and post-operative nasal anthropometric measurements and subjective assessments in patients undergoing Primary Rhinoplasty.

Sponsor:	None
Study Doctor:	Dr. Abir Chowdhury
Site:	All India Institute of Medical Sciences, Jodhpur

## **DESCRIPTION OF STUDY:**

The patient following Rhinoplasty and who desired for any reasons will be called and asked to take part in a medical research study. Before you decide to participate, you should read this form. This form, called an *Information and Consent Form*, explains the study. This form will tell you what you will have to do during the study and the risks and benefits of the study. This form may contain words or information that you do not understand clearly. If so, please ask the study doctor or the study staff to explain those words or information. You may take home an unsigned copy of this form to help you decide whether or not to participate in the study. You can also discuss your participation with family, friends or anyone you choose before making your decision. If you decide to participate in the study and sign this form, you will be given a signed and dated copy of this form to keep for your records. Do not sign this form unless the study doctor or study staffs have answered all your questions and you decide that you want to be a part of this study.

When reading this form, please note that the words "you" and "your" refer to the person in the study rather than to a legally authorized representative who might sign this form on behalf of the person in the study.

Participating in a research study is not the same as getting regular medical care. The purpose of regular medical care is to improve your health. The purpose of a research study is to gather information.

# About the Study:

The purpose of this research study is to compare pre and post-operative nasal anthropometric measurements and subjective assessments in patients undergoing Primary Rhinoplasty.

This study will evaluate various angles involved in rhinoplasty. You will also be evaluated on final outcome of your surgery and quality of life after regular intervals of surgery. The study is planned to include 41 patients who will undergo rhinoplasty from to Dec 2019 to June 2021. The patients will be assessed preoperatively, at the one month follow up; three months follow up and finally at six months follow up.

There may be other reasons why you are not eligible to participate in this study. The study doctor will talk to you about why you may or may not be eligible.

## **Study Conduct:**

This is a prospective cohort study in which the patients fulfilling inclusion/ exclusion criteria will be assessed.

## **Responsibilities of study subjects**

To participate in the study, you must tell your doctor if you are suffering from any physical or psychological illness or not and must be willing to follow all study procedures. You must follow the instructions you are given by the doctor or study staff.

## What else should I know about the study procedures?

The study doctor or a member of a study staff can answer any questions you may have about the study procedures.

#### Risks

There are no risks involved in this study.

### **Benefits**

Your participation in this study may benefit you directly in a way that your satisfaction levels with the surgery will be calculated. The assessment of quality of life after the surgery will also be assessed. The study will also help us and others to plan health care strategies for betterment of our clients seeking cosmetic nasal surgeries.

#### **Payment for participation:**

You will not get paid being in this study.

#### **Payment for investigations:**

Not applicable

### **New Information**

The study doctor will also tell you if new information become available.

#### Legal rights

By signing this information and consent form and the accompanying Informed Consent Form to participate in a Research Study, you are not waiving any of the legal rights that you have as a subject in a research study.

#### Source of funding

None

#### Confidentiality

Except where required by law or regulatory authorities, you will not be identified by name, address, telephone number or any other direct personal identifier in study records disclosed outside of the clinic.

Also individuals from Ethics Review Committee may also look and copy the health information generated or collected about you as part of this study, both to assure quality control and to analyze the information.

The results of this study conducted by the study doctor may be published or presented at meetings but will not include your name or any other information that reveals your identity.

Your authorization for use and disclosure of the health information generated or collected as part of study has no expiry date.

# **Voluntary participation / withdrawal**

Your participation in the study is voluntary. You may choose not to participate in the study or, if you agree to participate in the study at any time. This will not affect on your treatment in anyway.

Your participation in the study may also be terminated at any time, without your consent, under the following circumstances:

- 1. If you do not follow the instructions of the study doctor or the study staff;
- 2. If the study doctor determines that participating in the study is not appropriate for your condition; or
- 3. If the sponsor cancels the study.

If you choose not to participate in the study or to withdraw from the study or if your participation in the study is terminated, you will not have any penalty or lose any benefits to which you are otherwise entitled.

#### Questions

If you have questions about the study or your condition, you should contact the study doctor:

#### Dr. Abir Chowdhury

Department of Otorhinolaryngology

All India Institute of Medical Sciences, Jodhpur, Rajasthan

# If you have questions about the study or your rights as a research subject, you may contact

#### **Ethics Review Committee**

All India Institute of Medical Sciences, Jodhpur, Rajasthan

Do not sign this information and consent form or the accompanying Informed Consent form to participate in a research study unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

### ANNEXURE- D: PATIENT INFORMATION SHEET (HINDI)

# मरीज़ की जानकारी

शीर्षक : प्राथ मक राइनोप्लास्टी के दौर से गुजर रहे वयस्क रो गयों में प्री और पोस्टऑपरेटिव नाक एंथ्रोपोमेट्रिक माप और व्यक्तिपरक आकलन की तुलना

प्रायोजक: कोई नहीं अध्ययन डॉक्टर: डॉ अबीर चौधरी

स्थान :अ खल भारतीय आय् वंज्ञान संस्थान,जोधप्र

अध्ययन का ववरण

आपको मे डकल रिसर्च स्टडी में भाग लेने के लए कहा गया है। भाग लेने का फैसला करने से पहले, आपको इस फॉर्म को पढ़ना चाहिए। इस फॉर्म को एक सूचना और सहमति पत्र कहा जाता है। यह फॉर्म आपको बताएगा क अध्ययन के दौरान आपको क्या करना होगा और अध्ययन के जो खम और लाभ क्या होंगे। इस फ़ॉर्म में ऐसे शब्द या जानकारी हो सकती हैं जिन्हें आप स्पष्ट रूप से समझ नहीं सकते हैं। यदि ऐसा है, तो कृपया उन शब्दों या जानकारी को समझाने के लए अध्ययन डॉक्टर या अध्ययन कर्मचारियों से पूछें। अध्ययन में भाग लेना है या नहीं, यह तय करने में आपकी सहायता के लए आप इस फॉर्म की एक हस्ताक्षरित प्रति ल प ले सकते हैं। आप निर्णय लेने से पहले अपने परिवार, दोस्तों या कसी भी व्यक्ति के साथ अपनी भागीदारी पर चर्चा भी कर सकते हैं। यदि आप अध्ययन में भाग लेने और इस फॉर्म पर हस्ताक्षर करने का निर्णय लेते हैं, तो आपको अपने रिकॉर्ड रखने के लए इस फॉर्म की एक हस्ताक्षरित और दिनां कत प्रति दी जाएगी। इस फॉर्म पर हस्ताक्षर न करें जब तक क अध्ययन डॉक्टर या अध्ययन कर्मचारी ने आपके सभी सवालों का जवाब नहीं दिया है और आप तय करते हैं क आप इस अध्ययन का हिस्सा बनना चाहते हैं। इस फॉर्म को पढ़ने पर, कृपया ध्यान दें क "आप" और "आपका" शब्द कानूनी रूप से अ धकृत प्रतिनि ध के बजाय अध्ययन में व्यक्ति को संद र्भत करते हैं जो अध्ययन में व्यक्ति की तरफ से इस फॉर्म पर हस्ताक्षर कर सकते हैं।

एक शोध अध्ययन में भाग लेना निय मत च कत्सा देखभाल के समान नहीं है। निय मत च कत्सा देखभाल का उद्देश्य अपने स्वास्थ्य को बेहतर बनाना है। एक शोध अध्ययन का उद्देश्य जानकारी इका करना है। इस अध्ययन में होने से आपकी निय मत च कत्सा देखभाल नहीं बदली जाती है।

अध्ययन के बारे में:

इस शोध अध्ययन का उद्देश्य प्राथ मक राइनोप्लास्टी से ग्जरने वाले रो गयों में प्री और

पोस्ट-ऑपरेटिव नाक एंथ्रोपोमेट्रिक माप और व्यक्तिपरक आकलन की तुलना करना है। यह अध्ययन राइनोप्लास्टी में शा मल व भन्न कोणों का मूल्यांकन करेगा। सर्जरी के निय मत अंतराल के बाद आपकी सर्जरी और जीवन की गुणवत्ता के अंतिम परिणामों पर भी मूल्यांकन कया जाएगा। अध्ययन में 41 रो गयों को शा मल करने की योजना बनाई गई है, जो दिसंबर 2019 से जून 2021 तक राइनोप्लास्टी से गुजरेंगे। रो गयों का पूर्व-आकलन कया जाएगा और ऑपरेशन के एक महीने के बाद; तीन महीने के बाद और आखिरकार छह महीने फॉलोअप किया जाएगा।

इस अध्ययन में भाग लेने के योग्य नहीं होने के अन्य कारण भी हो सकते हैं। अध्ययन करने वाला डॉक्टर आपसे इस बारे में बात करेगा क आप पात्र क्यों हो सकते हैं या नहीं। अध्ययन आचरण:

यह एक संभा वत अध्ययन है जिसमें रो गयों को समावेशन / बहिष्करण मानदंडों को पूरा करने के लए सर्जरी से पहले और सर्जरी के 3 महीने बाद मूल्यांकन कया जाएगा। पूर्व में रहिनोप्लास्टी हो चुके रो गयों का मूल्यांकन दस्तावेजों से कया जायेगा अध्ययन वषयों की जिम्मेदारियां

अध्ययन में भाग लेने के लए, आपको अपने डॉक्टर को यह बताना होगा क क्या आप कसी भी शारीरिक या मनोवैज्ञानिक बीमारी से पी इत हैं या नहीं आपको डॉक्टर या अध्ययन कर्मचारियों द्वारा दिए गए निर्देशों का पालन करना होगा। अध्ययन प्र क्रयाओं के बारे में मुझे और क्या पता होना चाहिए? अध्ययन डॉक्टर या एक अध्ययन कर्मचारी के सदस्य अध्ययन प्र क्रयाओं के बारे में आपके कसी भी प्रश्न का उत्तर दे सकते हैं। जो खम इस अध्ययन में कोई जो खम शा मल नहीं है।

लाभ

इस अध्ययन में आपकी भागीदारी से आप सीधे इस तरह से लाभा वंत हो सकते है I अध्ययन हमारे और दूसरों को कॉस्मेटिक नाक सर्जरी की मांग करने वाले हमारे ग्राहक के सुधार के लए स्वास्थ्य देखभाल रणनीतियों की योजना बनाने में भी मदद करते हैं।

भागीदारी के लए भ्गतान:

आपको इस अध्ययन में भुगतान नहीं मलेगा।

जांच के लए भुगतान:

लागू नहीं

नई जानकारी

अध्ययन डॉक्टर आपको यह भी बताएगा क क्या नई जानकारी उपलब्ध हो गई है।

क़ानूनी अ धकार

एक शोध अध्ययन में भाग लेने के लए इस जानकारी और सहमति फॉर्म और साथ में सू चत सहमति फॉर्म पर हस्ताक्षर करके, आप अनुसंधान अध्ययन में कसी वषय के रूप में आपके पास कसी भी कानूनी अ धकार को छोड़ नहीं रहे हैं।

धन के स्रोत

कोई नहीं

#### गोपनीयता

कानून या नियामक प्रा धकरणों द्वारा जहां आवश्यक हो, सवाय इसके क आपको क्लिनिक के बाहर खुलासा अध्ययन में नाम, पता, टेलीफोन नंबर या कसी अन्य प्रत्यक्ष व्यक्तिगत पहचानकर्ता दवारा पहचाना नहीं जाएगा।

ए थक्स रिव्यू कमेटी के व्यक्ति भी गुणवत्ता नियंत्रण सुनिश्चित करने और जानकारी का वश्लेषण करने के लए, इस अध्ययन के हिस्से के रूप में आपके बारे में उत्पन्न या एकत्रित स्वास्थ्य जानकारी को देख और कॉपी कर सकते हैं।

अध्ययन डॉक्टर द्वारा कए गए इस अध्ययन के नतीजे बैठकों में प्रका शत या प्रस्तुत कए जा सकते हैं ले कन आपकी पहचान या कोई अन्य जानकारी शा मल नहीं होगी जो आपकी पहचान का खुलासा करे।

अध्ययन के हिस्से के रूप में उत्पन्न या एकत्रित स्वास्थ्य जानकारी के उपयोग और प्रकटीकरण के लए आपका प्रा धकरण कोई समाप्ति ति थ नहीं है।

स्वैच्छिक भागीदारी / वापसी

अध्ययन में आपकी भागीदारी स्वैच्छिक है। आप अध्ययन में भाग लेने का चयन कर सकते हैं या, यदि आप कसी भी समय अध्ययन में भाग लेने के लए सहमत हैं। यह वैसे भी आपके इलाज पर प्रभा वत नहीं होगा।

निम्न ल खत परिस्थितियों में, आपकी सहमति के बिना, अध्ययन में आपकी भागीदारी कसी भी समय समाप्त हो सकती है:

1. यदि आप अध्ययन डॉक्टर या अध्ययन कर्मचारियों के निर्देशों का पालन नहीं करते हैं;

2. यदि अध्ययन डॉक्टर निर्धारित करता है क अध्ययन में भाग लेना आपकी हालत के लए उपयुक्त नहीं है; या

3. अगर प्रायोजक अध्ययन रद्द कर देता है।

यदि आप अध्ययन में भाग लेने या अध्ययन से वापस लेने का चयन नहीं करते हैं या यदि अध्ययन में आपकी भागीदारी समाप्त हो जाती है, तो आपके पास कोई जुर्माना नहीं होगा या कोई लाभ नहीं होगा जिसके लए आप अन्यथा हकदार हैं।

प्रश्न

यदि आपके पास अध्ययन या आपकी स्थिति के बारे में कोई प्रश्न है, तो आपको अध्ययन डॉक्टर से संपर्क करना चाहिए:

डॉ अबीर चौधरी

पता

Otorhinolaryngology वभाग

अ खल भारतीय आयु वंज्ञान संस्थान, जोधपुर, राजस्थान

<u>यदि आपके पास शोध वषय के रूप में अध्ययन या आपके अ धकारों के बारे में कोई प्रश्न है,</u> तो आप संपर्क कर सकते हैं

नैतिकता समीक्षा स मति

अ खल भारतीय आयु वंज्ञान संस्थान, जोधपुर, राजस्थान

एक शोध अध्ययन में भाग लेने के लए इस जानकारी और सहमति फॉर्म या साथ में सू चत सहमति फॉर्म पर हस्ताक्षर न करें जब तक क आपको प्रश्न पूछने का मौका न हो और आपके सभी सवालों के संतोषजनक उत्तर प्राप्त न हों।

# ANNEXURE- E: CASE RECORD FORM

#### PATIENT PROFORMA

A. BIODATA

C.R.NO.:

- 1. Name
- 2. Age
- 3. Sex
- 4. Occupation
- 5. Address
- 6. Date of Examination
- **B. HISTORY**

#### ENT SYMPTOMS

1. Difficulty in breathing - Duration

-

-

-

2 Difficulty in hearing

-Tinnitus

-Ear discharge

-Neck swelling

Any nasal symptoms like discharge, nasal dryness, nasal obstruction, sneezing, post nasal discharge, headache and epistaxis.

Any throat symptoms like recurrent attacks of upper respiratory tract infections, sore throat.

Any history of dysphagia, odynophagia or dyspnea.

#### PAST MEDICAL HISTORY

-Any significant medical disease

-History of tuberculosis, diabetes mellitus, hypertension

-History of injections in the past

-History of trauma

-History of any operation in the past

-History of drug reactions in the past

-History of measles, mumps, rubella, meningitis, other febrile illness etc.

#### SOCIAL AND PERSONAL HISTORY

-Occupation

-Economic status

-Addictions:

Smoking, alcohol consumption

#### FAMILY HISTORY

#### C. CLINICAL EXAMINATION:

I. General Examination

-Built, Weight and Height

-Pulse rate

-Blood pressure

-Pedal edema

-Pallor

-Respiratory rate

-Clubbing

-Lymphadenopathy

-Jugular venous pressure

-Cyanosis

-Icterus

-Congested eyes

-Ascites

-Skin

#### **II. SYSTEMIC EXAMINATION**

-Cardiovascular system

-Central nervous system

-Gastrointestinal system

-Respiratory system

#### **III ENT EXAMINATION:**

EARS

Rt. Lt.

-Pre & Post auricular region –

-Pinna -

-External auditory canal -

Tympanic membrane -

**Hearing Assessment** 

-Rinne's test -

-Weber test –

- Absolute bone conduction

NOSE

TIP

Volume	I (+1, 2, 3)	(-1, 2, 3)				
Definition	I (+1, 2, 3)	(-1, 2, 3)				
Width	I (+1, 2, 3)	(-1, 2, 3)				
Position	IN (I, +, -)	EX (I, +, -)				
Rotation	IN (I, +, -)	EX (I, +, -)				
Projection	IN (I, +, -)	EX (I, +, -)				
RADIX						
Level	I (+1, 2, 3)	(-1, 2, 3)				
Depth	I (+1, 2, 3)	(-1, 2, 3)				
Angles	NFR deg	grees NFA	degree	es		
DORSUM						
Bony vault						
Height	I (+1, 2, 3)	(-1, 2, 3)				
Base Width	I V	V N				
Bone Length	II	L S				
Cartilage Vault						
Height	I (+1, 2, 3	( <b>-1</b> , <b>2</b> , <b>3</b> )				
Dorsal Width	I V	V N				
Length	I	L S				
BASE						
Columella						
Col-Lab angle		degrees		Shape		
Septum		I	L		R	
Nasal Spine		Ι		I	L	
-------------------------------	------------------------------	------------	--------------	---------------	------------	---
Alar b	Alar base					
Alar Width		I (+1, 2	I (+1, 2, 3)		(-1, 2, 3)	
Nostri	il/lobule	90% 80% 75		% 66% 50% 33%		
Nostri	il Shape	I	Α	R	Р	
OTH	ER					
Septu	m area					
Turbi	nate	R				L
Chin ]	Forehead					
Poster	rior Rhinoscopy					
THR	THROAT:					
-Tons	-Tonsils -					
-Poste	-Posterior pharyngeal wall -					
-Indir	-Indirect laryngoscopy					
-Orodental hygiene						
F. LABORATORY INVESTIGATIONS:						
1.	1. Complete hemogram					
2.	Renal function test: U	rea/Crea	tinine			
3.	Blood sugar					
4.	Urine Examination/Pr	oteinuria	l			
5.	Chest X-ray					

R

	Nasofrontal angle changes	Nasolabial angle changes	Nasal tip angle	Naso facial angle	Collumelar lobule angle	Lobule to nostril ratio
PRE- OPERATIVELY						
AFTER 1 MONTHS POST OPERATIVELY						
AFTER 3 MONTHS POST OPERATIVELY						
AFTER 6 MONTHS POST OPERATIVELY						

#### **OBJECTIVE ASSESSMENTS BY LIFE SIZE PHOTOGRAPH:**

NB: The objective assessment of the aesthetic index was performed through the application of the standard anthropometric measurement using patient life size photography, in which the normal values of the angles were measured and calculated through three standard photos (frontal, lateral and basal nasal views) which captured by the same photographer (before, and after the operation), in order of a certain a uniform size of the photography

.

# SUBJECTIVE ASSESSMENT BY RHINOPLASTY OUTCOME EVALUATION (ROE) QUESTIONNAIRE:

	Rhinoplasty outcomes evaluation (ROE)						
This follow proced	This questionnaire is designed to assist your surgeon in determining the best patient outcomes following rhinoplasty surgery. Your comments are confidential and may be used to refine surgical procedures for future patients. Please circle the number that best characterizes your current opinion regarding the following questions:						
1. How we	ell do you like the ap	pearance of you	ur nose?				
	Not at all 0	Soemwhat 1	Moderately 2	Very much 3	Completely 4		
2. How we	ell are you able to br	reathe through y	our nose?				
	Not at all 0	Soemwhat 1	Moderately 2	Very much 3	Completely 4		
3. How m	3. How much do you feel your friends and loved ones like your nose?						
	Not at all 0	Soemwhat 1	Moderately 2	Very much 3	Completely 4		
4. Do you	4. Do you think your current nasal appearance limits you social or professional activities?						
	Always 0	Usually 1	Sometimes 2	Rarely 3	Never 4		
5. How co	5. How confident are you that your nasal appearance is the best that it can be?						
	Not at all 0	Soemwhat 1	Moderately 2	Very much 3	Completely 4		
6. Would	6. Would you like to surgically alter the appearance or function of your nose?						
	Definitely 0	Most likely 1	Possibly 2	Probably not 3	No 4		

#### ANNEXURE- F: IEC CERTIFICATE



# अखिल भारतीय आयुर्विज्ञान संस्थान, जोधपुर All India Institute of Medical Sciences, Jodhpur संस्थागत नैतिकता समिति Institutional Ethics Committee

No. AIIMS/IEC/2020/2037

Date: 01/01/2020

#### ETHICAL CLEARANCE CERTIFICATE

Certificate Reference Number: AIIMS/IEC/2019-20/983

Project title: "Comparison of pre and post operative nasal anthropometric measurements and subjective assessment in adult patients undergoing primary rhinoplasty"

Nature of Project:	Research Project
Submitted as:	M.S. Dissertation
Student Name:	Dr.Abir Chowdhury
Guide:	Dr.Kapil Soni
Co-Guide:	Dr.Amit Goyal, Dr.Bikram Choudhury & Dr.Darwin Kaushal

This is to inform that members of Institutional Ethics Committee (Annexure attached) met on 23-12-2019 and after through consideration accorded its approval on above project. Further, should any other methodology be used, would require separate authorization.

The investigator may therefore commence the research from the date of this certificate, using the reference number indicated above.

Please note that the AIIMS IEC must be informed immediately of:

- Any material change in the conditions or undertakings mentioned in the document.
- Any material breaches of ethical undertakings or events that impact upon the ethical conduct of the research.

The Principal Investigator must report to the AIIMS IEC in the prescribed format, where applicable, bi-annually, and at the end of the project, in respect of ethical compliance.

AIIMS IEC retains the right to withdraw or amend this if:

- Any unethical principle or practices are revealed or suspected
- · Relevant information has been withheld or misrepresented

AIIMS IEC shall have an access to any information or data at any time during the course or after completion of the project.

On behalf of Ethics Committee, I wish you success in your research.

**Enclose:** 

1. Annexure 1

Dr. Pra Sharma Institutional Ethios Committee AIMS, Jodhpur

Page 1 of 2

Basni Phase-2, Jodhpur, Rajasthan-342005, Website: www.aiimsjodhpur.edu.in, Phone: 0291-2740741 Extn. 3109 Email: ethicscommittee@aiimsjodhpur.edu.in Annexure 1

### Institutional Ethics Committee All India Institution of Medical Sciences, Jodhpur

Meeting of Institutional Ethics committee held on 23-12-2019 at 10:00 AM at Committee Room, Admin Block AIIMS Jodhpur.

Following members were participated in the meeting:-

S/No.	Name of Member Qualification		Role/Designation in Ethics Committee
1.	Dr. F.S.K Barar	MBBS, MD (Pharmacology)	Chairman
2.	Justice N.N Mathur	LLB	Legal Expert
3.	Dr. Varsha Sharma	M.A (Sociology)	Social Scientist
4.	Mr. B.S.Yadav	B.Sc., M.Sc. (Physics), B.Ed.	Lay Person
5.	Dr. K.R.Haldiya	MD (General Medicine)	Clinician
6.	Dr. Arvind Mathur	MBBS, MS (General Medicine)	Clinician
7.	Dr. Surajit Ghatak	MBBS, MS (Anatomy)	Basic Medical Scientist
8.	Dr. Vijaya Lakshmi Nag	MBBS, MD (Microbiology)	Basic Medical Scientist
9.	Dr. Sneha Ambwani	MBBS, MD (Pharmacology)	Basic Medical Scientist
10.	Dr. Kuldeep Singh	MBBS, MD (Paediatric), DM (General Medicine)	Clinician
11.	Dr. Abhinav Dixit	MBBS, MD (Physiology), DNB (Physiology)	Basic Medical Scientist
12.	Dr. Pradeep Kumar Bhatia	MBBS, MD (Anaesthesiology)	Clinician
13.	Dr. Tanuj Kanchan	MBBS, MD (Forensic Medicine)	Basic Medical Scientist
14.	Dr. Pankaj Bhardwaj	MBBS, MD (CM&FM)	Clinician
15.	Dr. Praveen Sharma	M.Sc., Ph.D. (Biochemistry)	Member Secretary

Dr. Pravees Sharma Member secretary Institutional Ethics Committee AIIMS, Jodhpur

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